UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

August 20, 2014

MEMORANDUM

Subject: Efficacy Review for Sodium Chlorite Technical; EPA Reg. # 90094-1; DB Barcode: D419987.

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Applicant: DRS Laboratories, Inc.
9205 NW 101st St
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Formulation from the Label:

Active Ingredients	% by wt.
Sodium Chlorite*	80 %
Other Ingredients	20 %
Total	100 %

*Available Chlorine..... 125%

I. BACKGROUND

The product, Sodium Chlorite Technical (EPA Reg. no. 90094-1), is an EPA-approved industrial use only product to generate chlorine dioxide gas for water treatment. The applicant requested an amendment to the registration of this product to add use of this product to generate gaseous Chlorine dioxide for use in the registrant's Mini-CD System® to decontaminate biological safety cabinets. Published literature (6 articles) was submitted to support the new use.

This data package identified as D419987 contained a letter from the applicant's representative to EPA (dated February 18, 2014), one study (MRID Nos. 493202-01), Statements of No Data Confidentiality for the study, Mini-CD System's Instruction Manual (Version 4) and the proposed label (Master Label version 20140214).

II. USE DIRECTIONS

1. Relative humidity monitored and maintained within a range of 60-85% throughout the decontamination process and temperature should be 60° F (15° C) or higher.
2. Multiply the total volume of the BSC by 0.13 g/ft^3 (4.7 g/m^3) to determine the mass of GCD required to be generated. Multiply that value by the value of mass of GCD per unit mass of generating chemicals.
3. Allow the BSC to stand a minimum of 85 minutes from the initiation of gas generation with the assumption that the duration until peak concentration will be under 10 minutes.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sterilants for Porous and Non-Porous Surfaces within Sealed Enclosures and Vehicles (for Bacterial Spores Known to be Highly Resistant to Sterilants and Disinfectants)

The effectiveness of a sterilant within a sealed enclosure or vehicle may be supported by efficacy data from in-use testing (i.e., field testing) conducted according to an EPA-approved protocol such as "End-Use Protocol for Sterilization of Porous and Non-Porous Surfaces within Sealed Enclosures Using STERIS Vaporized Hydrogen Peroxide (VHP®) Technology" or "End-Use Protocol for Sterilization of Porous and Non-Porous Surfaces within Emergency Vehicle Using STERIS Vaporized Hydrogen Peroxide (VHP®) Technology." Biological Indicators (BIs) must show no growth for the marker organism after 7 days at 55ºC. Chemical indicators must show a qualitative color change indicative of hydrogen peroxide exposure. The hydrogen peroxide concentration in the spaces adjacent to the enclosure exterior or vehicle exterior must remain below 1 ppm during the sterilization cycle. Parameters for product application (i.e., temperature, relative humidity, vaporized hydrogen peroxide concentration, contact time) must be met for all four phases of the sterilization cycle.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 493202-01 "Efficacy of Gaseous Chlorine Dioxide as Delivered by the DRS Laboratories' Mini-CD System (MCS)" by J. Michael Kelley, PhD. Compilation of Published Studies. Completion date – February 14, 2014. Project Number 20140214.

This document is composed of 5 pages (pages 5 to 9) of efficacy discussion followed by 10 documents and articles as followed;

Attachment 1: “Validation Study for the Use of Chlorine Dioxide Gas as a Decontaminant for Biological Safety Cabinets” by H. Luftman (2008) and M. Regits (2008) on page 10.
Attachment 2: “Decontamination/Sterilization with Chlorine Dioxide Gas - Understanding the Kill Kinetics and Its Use in BSC Exposure Cycle Development” by R. Nyberg and Z. Born (2010) & R. Nyberg (2010) on page 25.
Attachment 3: “Exposure Times Necessary for Decontamination Gassing with Chlorine Dioxide” by R. Nyberg (2010) on page 30.
Attachment 4: “Gaseous Decontamination Methods in High-containment Laboratories” by D. Gordon, B. Carruthers, and S. Theriault (2012) on page 34.
Attachment 5: “A Discussion of Biological Safety Cabinet Decontamination Methods: Formaldehyde, Chlorine Dioxide, and Vapor Phase Hydrogen Peroxide” by M. Czarneski and K. Lorcheim (2011) on page 44.
Attachment 6: “Chlorine Dioxide Gas Sterilization under Square-Wave Conditions” by D. Jeng and A. Woodworth (1990) on page 53.
Attachment 7: NSF/ANSI Standard 49 (Annex G). Recommended Microbiological Decontamination Procedure. NSF/ANSI 39-2012 on page 60.
Attachment 8: CD Generation Part "A" Use in DRS's MCS: Gas Generation under Simulated Use Conditions on page 70.
Attachment 9: “Systematic Evaluation of the Efficacy of Chlorine Dioxide in Decontamination of Building Interior Surfaces Contaminated with Anthrax Spores” by V. Rastogi, et al (2010) on page 76.
Attachment 10: “B. Atrophaeus and G. Stearothermophilus Biological Indicators for Chlorine Dioxide Gas Decontamination” by H. Luftman and M. Regits (2008) on page 86.

The attachment 1 was the only article in which gaseous chlorine dioxide (CD) was generated using Mini-CD System® to decontaminate biological safety cabinets. Two methods of CD generation were used: one by injecting a specific mass of CD gas dependent upon the BSC volume (0.1g/ft^3 [~3g/L or ~3g/dm^3] with 80 min. exposure), and the other maintaining a constant CD gas concentration over the duration of the exposure (4.8 mg/L for 40 minutes and 2.8 mg/L for 55 minutes).

In method 1, five NuAire (Plymouth, MN) models of BSCs were used:
S602-600 (type A2 console, 6-foot width, 2.11m^3 volume)
NU437-400 (type A2 bench top, 4-foot, 1.28 m^3)
NU430-600 (type B2, 6-foot, 1.90 m^3)
NU427-400 (type Bl, 4-foot, 1.55 m^3)
NU427-600 (type Bl, 6-foot, 1.94 m^3)

In method 2, four BSCs manufactured by Baker, Inc. (Sanford, ME) models were used:
B60-112 (type Al, 6-foot width, volume 2.0 m^3)
SG-403 (type A2, 4-foot width, 1.4m3)
NCB-B6 (type Bl, 6-foot width 2.7 m^3)
4-TX (type B2, 4-foot width, 1.6 m^3)

Twelve (12) “Paper Biological Indicators” (BIs) per trial used in this study were all *Bacillus atrophaeus* (ATCC 9372 [*Bacillus subtilis* var. *niger*]).

The BIs were removed from the CD-exposed BSC within 2 hours of completing the gas removal. Sample preparation ensued within the next 1 to 12 hours.

The Agency's no growth results applicable to sterilants were recorded as followed:

Method 1: B2 6-foot, A2 6-foot, and B1 6-foot
Method 2 at 4.8mg/l for 40 min.: only A2 4-foot
Method 2 at 2.8 mg/l for 55 min.: A1 6-foot and B2 6-foot

V. CONCLUSION AND COMMENTS

1. The submitted data (published studies) **do not support** the use of the product, Sodium Chlorite Technical (EPA Reg. No. 90094-1), use as "Part A" in the generation of chlorine dioxide gas as delivered by the DRS Laboratories' Mini-CD System (MCS), as sterilant (decontaminant, fumigant) of Biological Safety Cabinets (BSCs) on porous and non-porous surfaces, when used in 85-minute cycle, at 0.13g/ft^3 (4.7g/m^3), under 60-85% relative humidity and over 60°F (15°C).

- *Geobacillus stearothermophilus* (ATCC 7953) spores as Biological Indicators (BIs) must be used on cellulose (paper) BIs and Steel BIs. Justification for changing BI' organism must be approved before generating data. Validation test was conducted on paper only BIs even though "Greater resistance of *Bacillus astrophaeus* to decontamination on steel versus paper substrates has been reported" in supporting documents (see attachment 10).

- Minimum of 3 product lots must be tested for each type of BSC claimed using DRS Laboratories' Mini-CD System (MCS) with zero growth. Not all BSCs claimed were tested with zero growth as results.

- BIs neutralization must be performed immediately after each cycle and subcultured; not up to 12 hours after treatment. Neutralization effectiveness control must be part of controls.

2. Registrant must conduct sterilization studies following the Agency guidelines and submit data for review. Any modification must be approved before generating data. It is advised to consult the Agency for generating a proposed protocol for efficacy evaluation of gaseous chlorine dioxide as delivered by the DRS Laboratories' Mini-CD System (MCS).